

### CLAIMS

1. Use of an estrogen receptor  $\beta$  (ER $\beta$ ) modulator for the manufacture of a medicament for the prevention and/or treatment of hormone dependant cancers and other proliferative disorders.
2. Use as in claim 1, wherein the ER $\beta$  modulator either antagonises or agonises ER $\beta$ .
3. Use as in claim 1, wherein the ER $\beta$  modulator is an ER $\beta$  agonist.
4. Use of 7-hydroxylated steroids and/or enzymes capable of catalysing the production of a 7-hydroxylated steroid for the manufacture of a medicament for the prevention and/or treatment of hormone dependant cancers and other proliferative disorders.
5. Use as in claim 4, wherein the 7-hydroxylated steroids are 7 $\alpha$ -hydroxylated steroids and/or 7 $\beta$ -hydroxylated steroids.
6. Use as in claim 5, wherein the steroids are selected from the group consisting of;
  - i) 7 $\alpha$ -hydroxy-DHEA (7DH),
  - ii) 7 $\alpha$ -hydroxy-pregnenolone,
  - iii) 7 $\alpha$ -hydroxy- $\beta$ -estradiol,
  - iv) 7 $\alpha$ ,3 $\beta$ ,17 $\beta$ -androstetriol,
  - v) 7 $\alpha$ ,3 $\beta$ ,17 $\beta$ -androstanetriol,
  - vi) 7 $\alpha$ -hydroxycholesterol,
  - vii) 7 $\alpha$ -25-hydroxycholesterol,
  - viii) 7 $\alpha$ -24-hydroxycholesterol,
  - ix) 7 $\alpha$ -27-hydroxycholesterol and
  - x) other 7 $\alpha$ -di-hydroxy and 7 $\alpha$ -multi-hydroxylated forms of cholesterol.
7. Use as in any preceding claim wherein the medicament is administered in association with a pharmaceutically acceptable carrier or diluent.

8. Use as in claims 1-4, wherein the medicament is directly or locally administered to the prostate and/or breast.
9. Use as in claims 1-4, wherein the hormone dependant cancer is prostate cancer or breast cancer.
10. Use as in claims 1-4, wherein the proliferative disorder is a disorder of the prostate or breast.
11. Use as in claim 10, wherein the disorder of the prostate is a disorder of prostate development or prostate ageing.
12. Use as in claim 10, wherein the disorder of the prostate is benign prostatic hyperplasia (BHP) and/or prostatitis.
13. Use as in claim 4, wherein the enzyme that produces 7-hydroxylated steroids is oxysterol 7 $\alpha$ -hydroxylase (CYP7B).
14. Use as in claim 4, wherein the enzyme capable of catalysing the production of a 7-hydroxylated steroid is modified.
15. Use as in claim 14, wherein the enzyme capable of catalysing the production of a 7-hydroxylated steroid is modified to improve substrate affinity.
16. Use as in claim 4, wherein the enzyme capable of catalysing the production of a 7-hydroxylated steroid is recombinantly or synthetically produced.
17. Use as in claim 4, wherein the 7-hydroxylated steroid is provided by contacting an enzyme capable of catalysing the production of said 7-hydroxylated steroid with a suitable substrate.

18. Use as in claim 4, wherein the 7-hydroxylated steroid is provided by contacting a cell comprising an enzyme capable of catalysing the production of said 7-hydroxylated steroid with a suitable substrate.
19. Use as in claim 18, wherein the cell is transformed with a vector containing a gene encoding an enzyme capable of catalysing the production of said 7-hydroxylated steroid.
20. Use as in claims 17 and 18, wherein the suitable substrate is a compound capable of being converted to a 7-hydroxylated steroid by an enzyme capable of catalysing the production of a 7-hydroxylated steroid.
21. Use as in claim 20, wherein the suitable substrate is selected from the group consisting of;
- i) dehydroepiandrosterone (DHEA),
  - ii) 3beta-androstenediol,
  - iii) 3β-androstenediol; and
  - iv) β-estradiol
22. Use of a nucleic acid encoding an enzyme capable of catalysing the production of a 7-hydroxylated steroid for the manufacture of a medicament for the treatment of hormone dependant cancers and other proliferative disorders.
23. Use as in claim 22, wherein the nucleic acid is contained within a nucleic acid vector.
24. Use as in claim 22, wherein the medicament is administered in association with a pharmaceutically acceptable carrier.
25. Use as in claim 22, wherein the enzyme capable of catalysing the production of a 7-hydroxylated steroid is oxysterol 7α-hydroxylase (CYP7B).

26. A method of detecting either a level of a 7-hydroxylated steroid or a level of an enzyme capable of catalysing the production of a 7-hydroxylated steroid or detecting a mutation in a sequence encoding an enzyme capable of catalysing the production of a 7-hydroxylated steroid, wherein the method comprises the steps of;

- d) providing a sample from a patient;
- e) detecting a level of 7-hydroxylated steroid or an enzyme capable of catalysing the production of a 7-hydroxylated steroid or ascertaining the sequence of the nucleic acid encoding said enzyme; and
- f) comparing said detected level or the sequence of said nucleic acid with a normal level or sequence.

27: The method according to claim 26 for use in detecting the efficacy of a drug used to treat hormone dependant cancers and other proliferative disorders.

28: The method of claim 26 for use in ascertaining the stage of a tumour.

29. The method of claim 26, wherein the patient is either a healthy person, a person suspected of having, predisposed to developing, or suffering from a hormone dependant cancers or other proliferative disorder.

30. The method of claim 26, wherein the sample is a biopsy.

31. The method of claim 30, wherein the biopsy is a prostate biopsy or breast tissue biopsy.

32. The method of claim 26, wherein the sample is a body fluid.

33. The method of claim 32, wherein the sample is selected from the group consisting of

- i) blood;
- ii) urine; and/or
- iii) semen.

34. The method of claim 26, wherein the normal sequence encodes a functional enzyme capable of catalysing the production of a 7-hydroxylated steroid.
35. The method of claim 26, wherein the normal sequence is a sequence that does not comprise a mutation which effects the expression of said functional enzyme.
36. The method of claim 26, wherein the level of 7-hydroxylated steroid or an enzyme capable of catalysing the production of a 7-hydroxylated steroid is detected by means of immunological detection techniques.
37. The method of claim 36, wherein the level of 7-hydroxylated steroid or an enzyme capable of catalysing the production of a 7-hydroxylated steroid is detected by ELISA.
38. The method of claim 26, wherein the level of an enzyme capable of catalysing the production of a 7-hydroxylated steroid is detected by Western blot.
39. The method of claim 26, wherein the level of an enzyme capable of catalysing the production of a 7-hydroxylated steroid is detected by PCR and associated techniques, for example RT-PCR, quantitative PCR and quantitative RT-PCR.
40. The method of claim 26, wherein the level of an enzyme capable of catalysing the production of a 7-hydroxylated steroid is detected by spectrophotometric and enzymatic reactions
41. A method of detecting a 7-hydroxylated steroid or an enzyme capable of catalysing the production of a 7-hydroxylated steroid in a patient, comprising administering to a patient an amount of a molecule capable of interacting with a 7-hydroxylated steroid or an enzyme capable of catalysing the production of a 7-hydroxylated steroid and detecting any complex comprising said molecule and said 7-hydroxylated steroid or enzyme capable of catalysing the production of a 7-hydroxylated steroid.

42. The method of claim 41, wherein the molecule capable of interacting with a 7-hydroxylated steroid or an enzyme capable of catalysing the production of a 7-hydroxylated steroid is an antibody.

43. The method of claims 41 and 42, wherein the molecule or antibody further comprises a radiolabel.

44. The method of claims 41 and 42, wherein the molecule or antibody further comprises a radioactive isotope.

45. A method for identifying agents capable of modulating the activity of an enzyme capable of catalysing the production of a 7-hydroxylated steroid, wherein said assay comprises the steps of:

- c) contacting an agent with a prostate cell comprising an enzyme capable of catalysing the production of a 7-hydroxylated steroid, in the presence of a substrate capable of being converted to a 7-hydroxylated steroid by said enzyme; and
- d) detecting an amount of substrate converted to a 7-hydroxylated steroid by said enzyme and comparing said level to a normal level.

46. Use of agents identified by the method of claim 45 for the treatment and/or prevention of hormone dependant cancers and other proliferative disorders.